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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,788	08/14/2001	Edward J. Noga	5051.519	9014

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EXAMINER	
BERTOGLIO, VALERIE E	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,788	Applicant(s) NOGA ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election/Restriction* .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3, drawn to an antimicrobial peptide, classified in classes 530 and 514, subclasses 300 and 2.

II. Claims 2 and 4 drawn to an antimicrobial peptide, classified in classes 530 and 514, subclasses 300 and 2.

III. Claims 5 and 6, drawn to an antibody that binds an antimicrobial peptide, classified in class 530, subclass 387.1.

IV. Claims 7-8, drawn to a nucleic acid encoding an antimicrobial peptide, classified in classes 536 and 536, subclasses 23.1 and 23.5.

V. Claims 9-10, drawn to a method of administering a nucleic acid, classified in class 514, subclass 44.

VI. Claims 11-12 and 14-16, drawn to a method of monitoring levels of an endobiotic peptide wherein the peptide comprises SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3, classified in class 435, subclass 4.

VII. Claims 11,13,14 and 17, drawn to a method of monitoring levels of a histone-like peptide, classified in class 435, subclass 4.

VIII. Claims 18 and 19, drawn to a method of screening compounds useful for treating stress wherein the peptide comprises SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3, classified in class 530, subclass 350.

IX. Claims 18 and 20, drawn to a method of screening compounds useful for treating stress wherein the peptide is a histone-like protein, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are patentably distinct because are materially and structurally different. The peptide of Invention I does not require the peptide of Invention II and the peptide of Invention II does not require the peptide of Invention I. The burden required to search Inventions I and II together would be undue.

Inventions I and III are patentably distinct because, the peptide can be used as an anti-microbial agent while the antibody can be used to detect the presence of antimicrobial compounds. The protocols and reagents required for the peptide and the antibody are materially distinct and separate. The burden required to search Inventions I and III together would be undue.

Inventions I and IV are patentably distinct because, the peptide can be used as an anti-microbial agent while the nucleic acid can be used to synthesize antimicrobial compounds. The protocols and reagents required for the compound and the nucleic acid are materially distinct and separate. The peptide is not necessary for the nucleic acid and the nucleic acid is not necessary for the peptide. The burden required to search Inventions I and III together would be undue.

Invention I and Invention V-VIII or IX are patentably distinct because, the peptide can be used as an anti-microbial agent in vitro while the methods of Invention V can be used to administer a nucleic acid to treat stress in vivo, the methods of Invention VI or

VII can be used to the freshness of food, and the methods of Invention VIII or IX can be used to screen compounds for use in treating stress in fish. The peptide is not necessary for the methods and the methods are not necessary for the peptide. The protocols and reagents required for the peptide and the methods are materially distinct and separate. The burden required to search Invention I and Invention V-VIII or IX together would be undue.

Inventions II and III are patentably distinct because, the peptide can be used as an anti-microbial agent while the antibody can be used to detect the presence of an antimicrobial compound. The protocols and reagents required for the peptide and the antibody are materially distinct and separate. The burden required to search Inventions II and III together would be undue.

Inventions II and IV are patentably distinct because, the peptide can be used as an anti-microbial agent while the nucleic acid can be used to synthesize antimicrobial compounds. The protocols and reagents required for the compound and the nucleic acid are materially distinct and separate. The peptide is not necessary for the nucleic acid and the nucleic acid is not necessary for the peptide. The burden required to search Inventions II and IV together would be undue.

Invention II and Invention V-VIII or IX are patentably distinct because, the peptide can be used as an anti-microbial agent in vitro while the methods of Invention V can be used to administer a nucleic acid to treat stress in vivo, the methods of Invention VI or VII can be used to assess the freshness of food, and the methods of Invention VIII or IX can be used to screen compounds for use in treating stress in fish. The peptide is not

necessary for the methods and the methods are not necessary for the peptide. The protocols and reagents required for the peptide and the methods are materially distinct and separate. The burden required to search Invention II and Invention V-VIII or IX together would be undue.

Inventions III and IV are patentably distinct because, the antibody can be used to detect the presence of antimicrobial compounds while the nucleic acid can be used to synthesize antimicrobial compounds. The protocols and reagents required for the compound and the nucleic acid are materially distinct and separate. The antibody is not necessary for the nucleic acid and the nucleic acid is not necessary for the antibody. The burden required to search Inventions III and IV together would be undue.

Invention III and Invention V-VIII or IX are patentably distinct because, the antibody can be used to detect the presence of antimicrobial compounds while the methods of Invention V can be used to administer a nucleic acid to treat stress in vivo, the methods of Invention VI or VII can be used to assess the freshness of food, and the methods of Invention VIII or IX can be used to screen compounds for use in treating stress in fish. The antibody is not necessary for the methods and the methods are not necessary for the antibody. The protocols and reagents required for the antibody and the methods are materially distinct and separate. The burden required to search Invention III and Invention V-VIII or IX together would be undue.

Invention IV and Invention V-VIII or IX are patentably distinct because, the nucleic acid can be used to synthesize antimicrobial compounds in vitro while the methods of Invention V can be used to administer a nucleic acid to treat stress in vivo,

the methods of Invention VI or VII can be used to assess the freshness of food, and the methods of Invention VIII or IX can be used to screen compounds for use in treating stress in fish. The nucleic acid is not necessary for the methods and the methods are not necessary for the nucleic acid. The protocols and reagents required for the antibody and the methods are materially distinct and separate. The burden required to search Invention IV and Invention V-VIII or IX together would be undue.

The methods of each of Inventions V-IX are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The purpose of Invention V is to administer a nucleic acid to combat stress in fish, the purpose of Invention VI and VII is to determine the health of fish by detecting an endbiotic peptide comprising SEQ ID NO:1, 2 or 3 (Invention VI) or comprising a histone-like protein (Invention VII), the purpose of Invention VIII and IX is to screen compounds useful for treating stress by detecting peptides comprising SEQ ID NO:1,2, or 3 (Invention VIII) or comprising a histone-like protein (Invention IX). The burden required to search Inventions V-IX together would be undue.

Sequence Election Requirement

Claims 1,5,7,12,16,19 read on patentably distinct Groups drawn to multiple SEQ ID Numbers [in particular, SEQ ID NO: 1, 2 or 3]. Each of the SEQ ID Numbers constitutes independent inventions, which are patentably distinct because each of the sequences is unrelated. As such, a further restriction is applied to the sequences. For

an elected Group drawn to a SEQ ID NO, the Applicants must further elect a single sequence.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, it has recently been decided by the Director of Biotechnology at the USPTO that searching more than one sequence per application will place an undue burden upon the Examiner and the Office. For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

PETER PARAS
PATENT EXAMINER

Valarie Bertoglio
Patent Examiner